2. CLASSIFICATION SYSTEMS AND FORMULARIES

Background

Classification systems and formularies are intertwined features of the way health plans establish what drugs are available to their enrollees. Formularies are essentially lists of covered drugs, and they are rarely presented without some type of classification system. But classification systems often serve other purposes for their users. This section describes classification systems and formularies, as well as the pharmacy and therapeutic (P&T) committees that insurers and pharmacy benefit managers (PBMs) use to make decisions.

To make order out of the thousands of pharmaceutical products on the market, insurers, hospitals, and other entities find it helpful to organize drugs into hierarchical classification systems. Systems are organized around a mix of therapeutic mechanisms, organ systems, diseases, and chemical structure. Every system is different, and there is little consensus about which methodology is best.

While classification schemes organize drugs into categories, the important function of formularies is to describe which drugs are covered by a health plan and how much enrollees must pay for those drugs. Payers ranging from private plans to the Veterans' Administration have relied on formularies and tiered pricing to manage pharmacy costs. Technically, Medicaid programs cannot use a formulary, but quite a few states have developed preferred drug lists (PDLs) that provide them a basis for negotiating supplemental rebates with manufacturers.

Methodology

In this project, we studied six classification schemes:

USP Model Guidelines
Redbook (based on AHFS)
VA National Drug File
FDA (based on AMA Drug Evaluation)
IMS Health Uniform System of Classification
CMS Drug Card Guidance

In addition, we studied publicly available formularies from ten entities:

Blue Cross/Blue Shield Federal Employees' Plan
Pacificare Federal Employees' Plan
Kaiser Permanente Mid-Atlantic Federal Employees' Plan
Medco "Preferred Prescription" plan
Presbyterian Health Plan
Connecticare
VA's Core Formulary
Florida Medicaid

Michigan Medicaid
Oregon Medicaid

These entities were chosen to represent a mix of federal employees' plans, private sector plans, and state Medicaid programs with a variety of approaches to pharmacy management. For each of these systems, we analyzed how the hierarchy is organized and how many drugs are listed. For the formularies, we analyzed the number of drugs covered by each formulary and whether the formulary would meet CMS' rules. We also interviewed the pharmacy director from each plan and Medicaid program about the formulary and the plan's Pharmacy and Therapeutics Committee.

Role, Structure, and Content of Classification Systems

Several of the formularies we studied used classification schemes developed by First Databank and Express Scripts. Medco, Pacificare, and the VA have their own classification schemes. In these classification schemes, the number of unique categories where drugs can be placed varies widely. As shown in Figure 1, IMS has the most, with 520 unique categories; by contrast, others such as Kaiser, Pacificare, and FDA have fewer than 100 unique categories. Classification systems had 1 to 4 levels of hierarchy, but classification systems with more levels of hierarchy do not necessarily have more unique categories.

The number of drugs listed in each scheme or formulary also varies widely. In the classification systems other than USP, drugs frequently are listed multiple times for each manufacturer, and sometimes for each form and strength of the drug. In contrast, USP and the health plan formularies are much more consolidated in their listing of drugs. Additional descriptive statistics about these classification schemes, such as the typical number of drugs placed at each level of hierarchy, are available in Appendix A.

Classification schemes may take very different approaches to classifying the same drug. For four high-volume drugs – Lipitor, Prevacid, Synthroid, and Zoloft -- we created a detailed crosswalk of the different ways that these drugs are classified. Looking in Redbook, USP, Blue Cross/Blue Shield FEP, and Medco, we found all places in the hierarchy where the drugs are located. We also collected the names of the other drugs located in each class with our four study drugs. The results of these detailed crosswalks are in Appendix B.

Figure 1. Number of Categories and Drugs Listed in Various Classification Schemes and Formularies

	Classification Schemes					Formularies						
	USP	Redbook	VA NDF	FDA	IMS	Pacificare	Kaiser	BC/BS	Connecticare	Medco	Presbyterian	VA
Levels of hierarchy	3	3	3	2	4	2	1	4	2	4	2	3
Unique categories	222	287	247	94	520	88	82	178	129	159	175	250

Drugs listed	956	25,740	16,641	16,602	10,123	749	707	1310	1574	1036	754	1086

Figure 2. Multiple Classifications for Zoloft

	USP instance 1	USP instance 2	Redbook	BCBS instance 1	BCBS instance 2	Medco
Level 1	Antidepressants	Anxiolytics	Central Nervous System Agents	Psychiatric	Psychiatric	Autonomic & CNS, Neurology & Psych
Level 2	Reputake Inhibitors	Antidepressants	Psychotherapeutic Agents	Depression/ Obsessive Compulsive Disorders	Anxiety	Psychotherapeutic Drugs
Level 3	SSRIs		Antidepressants			Antidepressant Agents
Level 4						SSRIs

As one example, Figure 2 shows the many ways that Zoloft is classified in these four schemes. This example shows differences in the fundamental nature of the classification systems: some are based on diagnosis (depression, anxiety), while others are based on body systems (central nervous system). Some systems put the drug in more than one place based on uses of the drug for different diagnoses, while others select just one location, based on the most common use (antidepressant). Finally, we note that some classification systems create a class specifically for SSRIs, while others stop at a less detailed classification.

In general, plans indicated that they used their classification schemes as a way to organize discussions about which drugs to include on their formulary. Most plans review coverage decisions on a class-by-class basis, coming back to each class once every year or two. They may also use classifications as a way to organize utilization data for review. With the exception of expensive drugs requiring prior authorization, however, plans do not track whether drugs are being used in the way described by the classification scheme.

Some plans choose an organizational scheme by default – they use the scheme that their pharmacy benefits manager (PBM) or their claims processor uses. Others have put in the time and effort to develop their own classification scheme, indicating that at one point the plan found value in controlling how drugs are classified. But in most cases the classification system is not a major consideration that drives decision-making about formularies.

The P&T Committee Process

The MMA includes several requirements for how plans develop their formularies through the P&T Committee process:

- A majority of members must be practicing physicians or pharmacists
- The committee must include two experts in care of elderly or disabled
- At least one physician and one pharmacist must be independent
- The committee's decisions must be binding as to which drugs are on the formulary

- The committee's role may be advisory on tier placement and utilization management approaches
- Decision-making must be based on evidence

Although not a comprehensive, nationally representative sample, our interviews with plan pharmacy directors provide some insights into how these rules relate to current P&T practice.

Physicians and Pharmacists. A majority (8/10) of plans have both doctors and pharmacists on their committees; the remaining two use only physicians.

Independence. Most plans stated that their committees are entirely independent (6/10). Presbyterian has a partially independent committee. The VA, Kaiser Permanente, and Connecticare have committees made up entirely of plan providers, and most likely would have to make a change to their committee if they had to meet the new rules.

Binding vs. Advisory Role. The large majority of P&T committees serve in an advisory role to plan managers. Managers often expressed that they reserve the right to override the committee's decision, even if that right is almost never used. The exception was Kaiser Permanente, in which staff physicians truly have final control over the formulary, and the health plan provides only technical support. Making the committee's role binding on which drugs must be on formulary may be a change for many plans in policy if not in daily practice.

Evidence-based Decision-making. Overall, P&T committees make their decisions based on therapeutic knowledge. Committees are usually not given cost data when they are evaluating a drug. Once committee clinical evaluations are given to plans, then plan managers take cost into consideration when making final coverage decisions. However, there are some exceptions where cost is considered simultaneously with clinical factors.

Plans gather evidence in a variety of ways:

- Kaiser creates tables and monographs from literature for physicians both on and off the committee. Physicians who are not on the committee may make recommendations about these drugs, which then go to the P&T committee for consideration.
- Oregon and Michigan Medicaid are involved with the multi-state Drug Effectiveness Review Project, which conducts evidence-based reviews to determine differences among drugs in a given class. These reviews serve as inputs to the states' decisions on which drugs go on the preferred list.
- Florida Medicaid works with a vendor (Provider Synergies) to bring evidence into its P&T committee meetings.
- BCBS FEHBP works with Clinical Pharmacy Associates, Inc. instead of with PBMs in order to obtain unbiased research and drug presentations for its P&T Committee.
- Presbyterian has two full-time pharmacists on staff whose sole responsibility is to gather evidence-based literature for its committee.

Committee Process. Committee size varies considerably. Among those that provided specifics, the smallest committee had 7 members (FL Medicaid) and the largest had 50 members (Connecticare). Meetings typically occur on a regular basis. Private plan meetings tend not to be open to the public, but Medicaid committee meetings are. One plan noted that they keep the identity of committee members secret to shield them from intense lobbying from manufacturers.

Plans tend to update coverage decisions within each class on a regular schedule. Two plans told us they update coverage decisions within each class every two years, and four told us they update coverage decisions within each class annually. Discussions about a new drug happen almost immediately after market entry. More than half of plans (6/10) specifically stated that they had an ongoing review of new drugs on the market.

Additional information gathered from plan pharmacy directors is available in Appendix C. The Appendix describes, for each plan we interviewed, additional detail on the questions outlined above about the P&T Committee process as well as structural questions about how each formulary is organized.

Policy Implications: Classification Systems, Formularies, and P&T Committees

The findings of this project suggest that classification systems are less substantively important to the plans and PBMs than the formularies themselves. Health plans and PBMs may use classification systems as a technical tool to organize their formularies, but they do not seem to be critical to the design of the formularies. Classification can be important in displaying formularies for use by enrollees and providers, but it may not be the case that they use the full detail of their classification system for this purpose. Classification systems, however, are important in applying the rules determined by the MMA in whether plan formularies are adequate to ensure that they do not discriminate against certain groups of beneficiaries.

The empirical findings of this project on P&T committees are based on interviews with only ten pharmacy directors, so they may not provide definitive findings. But there are indications that current practice is in compliance with some of the MMA and CMS requirements, but not others. Current practice would generally support the MMA requirements for including physicians and pharmacists and would even allow stronger requirements. But committees may not have as much independence as required by the statute. Most plans do use evidence in making formulary decisions, although they have different ways of employing evidence.